REMARKS

Claims 1-63 are pending in the instant application. In the Office Action mailed June 16, 2004, the Examiner rejects claims 1, 3, 12, 16, 18, 21, 22, 33-43, 45, 47-52, 54, 55, 59, 62, and 63. Claims 2, 4-11, 13-15, 17, 19, 20, 23-32, 44, 46, 53, 56-58, 60, and 61 are withdrawn. The Specification has been amended to correct typographical errors.

By virtue of the amendments to the claims presented above, independent claim 55 is amended. Based on the amendments and remarks made herein, Applicants respectfully request that the rejections be withdrawn and that the application be passed to allowance.

1. Remarks on Paragraph 3 of the Office Action mailed on June 16, 2004: Rejection of Claims 1, 12, 16, 21, 34, 35, 42, 47, and 63 Under 35 U.S.C. §102(b)

In the Office Action mailed June 16, 2004, the Examiner rejects claims 1, 12, 16, 21, 34, 35, 42, 47, and 63 as being unpatentable under 35 U.S.C. §102(b) over Australian Patent Application No. AU 199941153 to Lucas (hereinafter "the Lucas application").

With respect to claims 1 and 42, the Examiner believes the Lucas application discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon (page 3, lines 18-23 and Figures 1 and 2).

Claim 1 is directed to an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the device including a fluid-absorbent body having an application region for projection within the vestibule; and a formulation including a therapeutic agent positioned substantially within the application region. Contrary to the disclosure of the Lucas application, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Lucas application is not disclosed as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, and thus cannot have a therapeutic agent positioned substantially within that application region.

Claim 42 is directed to a method for producing an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the method including manufacturing an absorbent device having a fluid-absorbent body having an application region for projection within the vestibule; and locating a formulation including the therapeutic agent substantially within the application region. Contrary to the disclosure of the Lucas application, the

Applicants' present invention is not directed to a tampon, but is in fact directed in part to producing an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Lucas application is not disclosed as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, and thus cannot locate a formulation including a therapeutic agent substantially within that application region.

Claim 12 is directed to the device of claim 1, wherein the therapeutic agent is a powder. Claim 16 is directed to the device of claim 1, wherein the formulation including the therapeutic agent is substantially a solid. Claim 21 is direct to the device of claim 1, wherein the therapeutic agent is adapted to treat dysmenorrhea. Claims 12, 16, and 21 are dependent claims that depend from an allowable independent claim, and are thus allowable themselves for the reasons stated above with respect to claim 1.

With respect to claims 34 and 47, the Examiner believes the Lucas application discloses a therapautic agent that is applied to the surface of a tampon body. Claim 34 is directed to the device of claim 1, wherein the body includes a surface, and wherein the formulation including a therapeutic agent is applied to the surface. Claim 47 is directed to the method of claim 42, wherein the body has a surface, and wherein the locating act includes applying the formulation including a therapeutic agent to the surface. As stated above with respect to claims 1 and 42, from which these two claims depend, respectively, and contrary to the disclosure of the Lucas application, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Lucas application is not disclosed as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, and thus cannot have a therapeutic agent positioned substantially within that application region. As a result, the Lucas application cannot disclose applying a formulation including a therapeutic agent to the surface of such an absorbent body.

With respect to claim 35, the Examiner believes the Lucas application discloses a therapautic agent that is applied to the surface of a tampon body. Claim 35 is directed to the device of claim 1, wherein the body is constructed from a material, and wherein the formulation including a therapeutic agent is applied to the material before the body is constructed. As stated above with respect to claim 34, and contrary to the disclosure of the Lucas application, the

Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Lucas application is not disclosed as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, and thus cannot have a therapeutic agent positioned substantially within that application region. As a result, the Lucas application cannot disclose applying a formulation including a therapeutic agent to the surface of such an absorbent body.

With respect to claim 63, the Examiner believes the Lucas application discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon. Claim 63 is direct to an absorbent device including a fluid-absorbent body having an application region for projection within the vestibule of a wearer; and a formulation including a therapeutic agent, wherein the application region is adapted to contact and deliver the therapeutic agent through the non-cornified epithelium of the labia. Contrary to the disclosure of the Lucas application, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device including a fluid-absorbent body having an application region for projection within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Lucas application is not disclosed as having an application region for projection within the vestibule of a wearer, nor does the device of the Lucas application have an application region that is adapted to contact and deliver the therapeutic agent through the non-cornified epithelium of the labia. A tampon does not contact the non-cornified epithelium of the labia as described in the instant application, and therefore cannot deliver a therapeutic agent through the non-cornified epithelium of the labia, as described in the instant application.

In view of the remarks set forth in this section, Applicants respectfully submit that claims 1, 12, 16, 21, 34, 35, 42, 47, and 63 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

2. Remarks on Paragraph 4 of the Office Action mailed on June 16, 2004: Rejection of Claims 1, 21, 22, 39, 40, 42, 43, 55, and 62 Under 35 U.S.C. §102(b)

In the Office Action mailed June 16, 2004, the Examiner rejects claims 1, 21, 22, 39, 40, 42, 43, 55, and 62 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 6,086,909 to Harrison et al. (hereinafter "the Harrison patent").

With respect to claims 1, 42, and 55, the Examiner believes the Harrison patent discloses a tampon and method for producing a tampon comprising a fluid-absorbent body 24 and a therapeutic agent 28 located within an application region of the tampon (Figure 4).

Claim 1 is directed to an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the device including a fluid-absorbent body having an application region for projection within the vestibule; and a formulation including a therapeutic agent positioned substantially within the application region. Contrary to the disclosure of the Harrison patent, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Harrison patent is not disclosed as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, and thus cannot have a therapeutic agent positioned substantially within that application region.

Claim 42 is directed to a method for producing an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the method including manufacturing an absorbent device having a fluid-absorbent body having an application region for projection within the vestibule; and locating a formulation including the therapeutic agent substantially within the application region. Contrary to the disclosure of the Harrison patent, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to producing an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Harrison patent is not disclosed as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, and thus cannot locate a formulation including a therapeutic agent substantially within that application region.

Claim 55 as amended is directed to a method of delivering a therapeutic agent through the non-cornified epithelium of the labia of a wearer, the method including disposing an absorbent article at least partially within the vestibule of the wearer, the absorbent article being adapted to contact the non-cornified epithelium and deliver the therapeutic agent. Contrary to the disclosure of the Harrison patent, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to producing an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line

24 to page 15, line 8). The Harrison patent does not disclose disposing an absorbent article at least partially within the vestibule of the wearer, wherein the absorbent article is adapted to contact the non-cornified epithelium and deliver a therapeutic agent.

With respect to claims 21, 39, and 40, the Examiner directs the Applicant to the Harrison patent (Abstract and col. 13, lines 34-60). Claim 21 is direct to the device of claim 1, wherein the therapeutic agent is adapted to treat dysmenorrhea. Claim 39 is directed to the device of claim 1, wherein the formulation including a therapeutic agent includes a hydrogel material. Claim 40 is directed to the device of claim 1, wherein the formulation including a therapeutic agent includes a foam component. First, claims 21, 39, and 40 are dependent claims that depend from an allowable independent claim, and are thus allowable themselves for the reasons stated above with respect to claim 1. Second, with respect to claim 39 and 40, the creams, ointments, etc. (Abstract and col. 13, lines 34-60) referenced by the Examiner are disclosed in the Harrison patent as acting alone with a drug. The use of such substances incorporates no absorbent device, and particularly not an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the device including a fluid-absorbent body having an application region for projection within the vestibule; and a formulation including a therapeutic agent positioned substantially within the application region.

With respect to claim 22, the Examiner believes the Harrison patent discloses the claimed therapeutic agents (col. 4, lines 43-59). Claim 22 is directed to the device of claim 1, wherein the therapeutic agent is selected from the group consisting of aspirin, ibuprofen, indomethacin, phenylbutazone, bromfenac, sulindac, nabumetone, ketorolac, mefenamic acid, and naproxen. Claim 22 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 1.

With respect to claims 43 and 62, the Examiner believes the Harrison patent discloses a mucoadhesive (col. 2, lines 60-63). Claim 43 is directed to method of claim 42, further comprising applying a mucoadhesive adapted to enhance the contact between the absorbent article and a non-cornified epithelium of the wearer. In addition to the reasons stated above for the allowability of claim 42, from which claim 43 depends, the Harrison patent does not disclose a mucoadhesive adapted to enhance the contact between the absorbent article and a non-cornified epithelium of the wearer. The Harrison patent specifically discloses contact with the vaginal epithelium of a user (see col. 3, lines 12-18; col. 4, lines 16-19; col. 7, lines 8-10; col. 11, lines 29-37; among others).

Claim 62 is directed to the method of claim 55, wherein delivery of the therapeutic agent is effected by combining the therapeutic agent with a mucoadhesive that enhances the contact

between the absorbent article and the non-cornified epithelium. In addition to the reasons stated above for the allowability of claim 55, from which claim 62 depends, the Harrison patent does not disclose a mucoadhesive adapted to enhance the contact between the absorbent article and a non-cornified epithelium of the wearer. The Harrison patent specifically discloses contact with the vaginal epithelium of a user (see col. 3, lines 12-18; col. 4, lines 16-19; col. 7, lines 8-10; col. 11, lines 29-37; among others).

In view of the remarks set forth in this section, Applicants respectfully submit that claims 1, 21, 22, 39, 40, 42, 43, 55, and 62 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

3. Remarks on Paragraph 5 of the Office Action mailed on June 16, 2004: Rejection of Claims 1, 3, 16, 18, 36-39, 41, 42, 45, 48-51, 52, 55, and 59 Under 35 U.S.C. §102(b)

In the Office Action mailed June 16, 2004, the Examiner rejects claims 1, 3, 16, 18, 36-39, 41, 42, 45, 48-51, 52, 55, and 59 as being unpatentable under 35 U.S.C. §102(b) over U.S Patent No. 3,490,454 to Goldfarb et al. (hereinafter "the Goldfarb patent").

With respect to claims 1, 3, 18, 38, 42, 45, 51, 52, and 55, the Examiner believes the Goldfarb patent discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer and contacting the non-cornified epithelium, and that the Goldfarb patent discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14).

Claim 1 is directed to an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the device including a fluid-absorbent body having an application region for projection within the vestibule; and a formulation including a therapeutic agent positioned substantially within the application region. First, the Examiner does not assert that the Goldfarb patent discloses every element of claim 1. The device of the Goldfarb patent does not have (and the Examiner does not assert that it has) an application region for projection within the vestibule, and thus cannot have a therapeutic agent positioned substantially within that application region. Second, contrary to the Examiner's assertion, the device of the Goldfarb patent is not disclosed as being configured for partial disposition within the vestibule of a wearer. There is no discussion in the Goldfarb patent of a vestibule or any anatomical features (such as labia) associated with a vestibule. The device of the Goldfarb patent has no structure or capability of being configured for partial disposition within the vestibule, as outlined in the instant application, and the Examiner has not pointed to any disclosure leading to

her conclusion. In fact, the Goldfarb patent states that the opposite is the case, that a "particularly preferred type of feminine napkin is of the construction shown in FIGURE 1 which comprises an absorbent portion designated generally as 1 having a shape generally approximating the shape of the exterior surface of the female pubic area to which it is to be applied." (col. 3, lines 18-22; emphasis added). Third, and with respect to the Examiner's second point, and contrary to the disclosure of the Goldfarb patent, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). Finally, the stated purpose of the device of the Goldfarb patent is to address menstrual discharge once it is resident in a catamenial product: to obviate odors and to combat bacterial growth within such catamenial product (see col. 1, lines 66-69; col. 2, lines 13-16; col. 2, lines 34-42; col. 5, lines 30-35; among others). There is no substantive disclosure in the Goldfarb patent of treating the user of a catamenial product; consequently, the substances disclosed in the Goldfarb patent are not therapeutic agents. The substances disclosed in the Goldfarb patent are simply chemicals used to deodorize, de-color, or otherwise alter menstrual discharge.

Claim 42 is directed to a method for producing an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the method including manufacturing an absorbent device having a fluid-absorbent body having an application region for projection within the vestibule; and locating a formulation including the therapeutic agent substantially within the application region. First, the Examiner does not assert that the Goldfarb patent discloses every element of claim 42. The Goldfarb patent does not disclose (and the Examiner does not assert that it discloses) an application region for projection within the vestibule, and thus cannot locate a formulation including a therapeutic agent substantially within that application region. Second, contrary to the Examiner's assertion, the device of the Goldfarb patent is not disclosed as being configured for partial disposition within the vestibule of a wearer. There is no discussion in the Goldfarb patent of a vestibule or any anatomical features (such as labia) associated with a vestibule. The device of the Goldfarb patent has no structure or capability of being configured for partial disposition within the vestibule, as outlined in the instant application, and the Examiner has not pointed to any disclosure leading to her conclusion. In fact, the Goldfarb patent states that the opposite is the case, that a "particularly preferred type of feminine napkin is of the construction shown in FIGURE 1 which comprises an absorbent portion designated generally as 1 having a shape generally approximating the shape of the exterior surface of the female pubic area to which it is to be applied." (col. 3, lines 18-22; emphasis added). Third, with respect to the Examiner's second point, and contrary to the disclosure of the Goldfarb patent, the

Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). Finally, the stated purpose of the device of the Goldfarb patent is to address menstrual discharge once it is resident in a catamenial product: to obviate odors and to combat bacterial growth within such catamenial product (see col. 1, lines 66-69; col. 2, lines 13-16; col. 2, lines 34-42; col. 5, lines 30-35; among others). There is no substantive disclosure in the Goldfarb patent of treating the user of a catamenial product; consequently, the substances disclosed in the Goldfarb patent are not therapeutic agents. The substances disclosed in the Goldfarb patent are simply chemicals used to deodorize, de-color, or otherwise alter menstrual discharge.

Claim 51 is directed to an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the device including a fluid-absorbent body having an application region for projection within the vestibule; and a means for carrying a formulation including the therapeutic agent within the application region. First, the Examiner does not assert that the Goldfarb patent discloses every element of claim 51. The device of the Goldfarb patent does not have (and the Examiner does not assert that it has) an application region for projection within the vestibule, and thus cannot have means for carrying a formulation including a therapeutic agent within that application region. Second, contrary to the Examiner's assertion, the device of the Goldfarb patent is not disclosed as being configured for partial disposition within the vestibule of a wearer. There is no discussion in the Goldfarb patent of a vestibule or any anatomical features (such as labia) associated with a vestibule. The device of the Goldfarb patent has no structure or capability of being configured for partial disposition within the vestibule, as outlined in the instant application, and the Examiner has not pointed to any disclosure leading to her conclusion. In fact, the Goldfarb patent states that the opposite is the case, that a "particularly preferred type of feminine napkin is of the construction shown in FIGURE 1 which comprises an absorbent portion designated generally as 1 having a shape generally approximating the shape of the exterior surface of the female pubic area to which it is to be applied." (col. 3, lines 18-22; emphasis added). Third, with respect to the Examiner's second point, and contrary to the disclosure of the Goldfarb patent, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). Finally, the stated purpose of the device of the Goldfarb patent is to address menstrual discharge once it is resident in a catamenial product: to obviate odors and to combat bacterial growth within such catamenial product (see col. 1, lines 66-

69; col. 2, lines 13-16; col. 2, lines 34-42; col. 5, lines 30-35; among others). There is no substantive disclosure in the Goldfarb patent of treating the user of a catamenial product; consequently, the substances disclosed in the Goldfarb patent are not therapeutic agents. The substances disclosed in the Goldfarb patent are simply chemicals used to deodorize, de-color, or otherwise alter menstrual discharge.

Claim 55 as amended is directed to a method of delivering a therapeutic agent through the non-cornified epithelium of the labia of a wearer, the method including disposing an absorbent article at least partially within the vestibule of the wearer, the absorbent article being adapted to contact the non-cornified epithelium and deliver the therapeutic agent. First, the Goldfarb patent does not disclose disposing an absorbent article at least partially within the vestibule of the wearer, and thus the absorbent article cannot be adapted to contact the non-cornified epithelium and deliver the therapeutic agent. Similarly, and contrary to the Examiner's assertion, the device of the Goldfarb patent is not disclosed as being capable of partial disposition within the vestibule of a wearer. There is no discussion in the Goldfarb patent of a vestibule or any anatomical features (such as labia) associated with a vestibule. The device of the Goldfarb patent has no structure or capability of being configured for partial disposition within the vestibule, as outlined in the instant application, and the Examiner has not pointed to any disclosure leading to her conclusion. In fact, the Goldfarb patent states that the opposite is the case, that a "particularly preferred type of feminine napkin is of the construction shown in FIGURE 1 which comprises an absorbent portion designated generally as 1 having a shape generally approximating the shape of the exterior surface of the female pubic area to which it is to be applied." (col. 3, lines 18-22; emphasis added). Next, with respect to the Examiner's second point, and contrary to the disclosure of the Goldfarb patent, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). Finally, the stated purpose of the device of the Goldfarb patent is to address menstrual discharge once it is resident in a catamenial product: to obviate odors and to combat bacterial growth within such catamenial product (see col. 1, lines 66-69; col. 2, lines 13-16; col. 2, lines 34-42; col. 5, lines 30-35; among others). There is no substantive disclosure in the Goldfarb patent of treating the user of a catamenial product; consequently, the substances disclosed in the Goldfarb patent are not therapeutic agents. The substances disclosed in the Goldfarb patent are simply chemicals used to deodorize, de-color, or otherwise alter menstrual discharge.

Claim 3 is directed to the device of claim 1, wherein the body includes a cover having a surface, and wherein the therapeutic agent is coupled to the surface. Claim 18 is directed to the

device of claim 1, wherein the formulation including the therapeutic agent is encapsulated. Claim 38 is directed to the device of claim 1, wherein the body has an interstitial space, and wherein the formulation including a therapeutic agent is interspersed within the interstitial space. Claims 3, 18, and 38 are dependent claims that depend from an allowable independent claim, and are thus allowable themselves for the reasons stated above with respect to claim 1.

Claim 45 is directed to the method of claim 42, wherein the manufacturing act includes manufacturing a body with cover having a surface, wherein the formulation including the therapeutic agent is coupled to the surface. Claim 45 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 42. Claim 52 is directed to the device of claim 51, wherein the application region has a surface, and wherein the carrying means is substantially positioned adjacent the surface. Claim 52 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 51.

With respect to claims 36 and 49, the Examiner believes the Goldfarb patent discloses an apertured web because the Goldfarb patent discloses an open or gauze nonwoven (col. 3, lines 53-54 and col. 4, lines 8-14). Claim 36 is directed to the device of claim 1, wherein the body includes an apertured web, and wherein the formulation including a therapeutic agent is contained in the apertured web. Claim 49 is directed to the method of claim 42, wherein the manufacturing act includes manufacturing the body to include an apertured web, and wherein the locating act includes containing the formulation including a therapeutic agent in the apertured web. In addition to the reasons stated above for the allowability of claim 1, from which claim 36 depends, and to the reasons stated above for the allowability of claim 42, from which claim 49 depends, the Goldfarb patent does not disclose an apertured web, and wherein the formulation including a therapeutic agent is contained in the apertured web. The Goldfarb patent discloses an "open, non-woven fabric" at col. 3, lines 56-57, but this is far from disclosing an apertured web as described in the instant application at page 21, lines 10-19.

With respect to claim 37, the Examiner believes the Goldfarb patent discloses the therapeutic agent applied to creped tissue (col. 3, lines 34-44). Claim 37 is directed to the device of claim 1, wherein the formulation including a therapeutic agent is applied to degradable fibers. Claim 37 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 1.

With respect to claim 39, the Examiner believes the Goldfarb patent discloses a therapeutic agent as a hydrogel (col. 6, lines 45-75). Claim 39 is directed to the device of claim 1, wherein the

formulation including a therapeutic agent includes a hydrogel material. In addition to the reasons stated above for the allowability of claim 1, from which claim 39 depends, the Goldfarb patent lists a number of materials from which its microcapsules are made, but none of these are hydrogels. In addition, the colloid, etc. materials are used in the Goldfarb patent to form the microcapsule walls, and are separate from the active ingredients within the microcapsules.

With respect to claim 41, the Examiner believes the Goldfarb patent discloses a therapeutic agent comprising a polymeric material (col. 8, lines 8-38). Claim 41 is directed to the device of claim 1, wherein the formulation including a therapeutic agent includes a polymeric material. Claim 41 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 1.

With respect to claims 48 and 50, the Examiner believes the Goldfarb patent discloses the agent is applied to various layers and between layers of the absorbent product. Claim 48 is directed to the method of claim 42, wherein the manufacturing act includes manufacturing the body from a material, and wherein the locating act includes applying the formulation including a therapeutic agent to the material before the body is manufactured. Claim 50 is directed to the method of claim 42, wherein the locating act includes producing the formulation including a therapeutic agent integrally with the device. Claims 48 and 50 are dependent claims that depend from an allowable independent claim, and are thus allowable themselves for the reasons stated above with respect to claim 42.

With respect to claim 59, the Examiner believes the Goldfarb patent discloses delivery of a therapeutis agent effect by melting a solid (col. 7, lines 1-8). Claim 59 is directed to the method of claim 55, wherein delivery of the therapeutic agent is effected by melting a solid. Claim 59 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 55.

In view of the remarks set forth in this section, Applicants respectfully submit that claims 1, 3, 16, 18, 36-39, 41, 42, 45, 48-51, 52, 55, and 59 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

4. Remarks on Paragraph 8 of the Office Action mailed on June 16, 2004: Rejection of Claim 33 as Obvious

In the Office Action mailed June 16, 2004, the Examiner rejects claim 30 as being unpatentable under 35 U.S.C. §103(a) over the Lucas application in view of U.S. Patent No. 5,585,277 to Bowie et al. ("the Bowie patent"). Applicants respectfully traverse the rejection.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Piasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Lucas application for modifying its teachings with the teachings of the Bowie patent.

Claim 33 is directed to the device of claim 1, wherein the formulation includes a ligand adapted to target the therapeutic agent. Neither of the two cited references (the Lucas application and the Bowie patent) disclose the claimed device. The Examiner improperly "picked and chose" the components from the two references using the claimed invention as a template in order to form the rejection.

In the Office Action mailed June 16, 2004, the Examiner states "It would have been obvious to one having ordinary skill in the art to modify the therapeutic agent of Lucas with a ligand for the benefits disclosed in Bowie." In this Office Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The sole motivation asserted by the Examiner is one of gaining "the benefits disclosed in Bowie." It is unclear how reading the "benefits disclosed in Bowie" would motivate one to look to another reference. The "benefits disclosed in Bowie" purport to be gained by Bowie alone. There is also no motivation in the Lucas application to look beyond its four corners to gain any benefits. There is, therefore, no motivation within the patents to apply the teachings of one to the other. The Examiner does not adequately state why one of ordinary skill would read the Lucas application and then look to the Bowie patent to convert one device to the another device to arrive at the device of claim 33.

Further, the motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner has pointed to no disclosure within either patent that one of skill in the art would look to for such motivation or teaching. Again, the Examiner has not explained why one would look at device identified in the Lucas application and be motivated to change it by applying the teaching of

the Bowie patent. The Examiner has failed to identify how the cited references suggest the desirability of modifying the device of the Lucas application to include components from the Bowie patent. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of claim 33 from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)[1]. For at least these reasons, Applicants assert that a *prima facie* case of obviousness has not been made and that claim 33 is patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that the prior art reference (or references when combined) teach or suggest all the claim limitations. And by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the device of the Lucas application to include components from the Bowie patent.

As discussed above with respect to claim 1, the Lucas application does not teach or suggest all of the claim limitations. Claim 1 is directed to an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the device including a fluid-absorbent body having an application region for projection within the vestibule; and a formulation including a therapeutic agent positioned substantially within the application region. Contrary to the disclosure of the Lucas application, the Applicants' present invention is not directed to a tampon, but is in fact directed in part to an absorbent device configured for partial disposition within the vestibule of a wearer, as described in detail in the present application (see particularly page 4, line 24 to page 15, line 8). The device of the Lucas application is not disclosed as being configured for partial disposition within the vestibule of a wearer, and does not have an application region for projection within the vestibule, and thus cannot have a therapeutic agent positioned substantially within that application region.

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[1] "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

The Bowie patent does not correct these deficiencies because it does not teach or suggest an absorbent device configured for partial disposition within the vestibule of a wearer, and adapted to deliver a therapeutic agent, the device including a fluid-absorbent body having an application region for projection within the vestibule; and a formulation including a therapeutic agent positioned substantially within the application region. Nor does Bowie teach or suggest the subject matter of claim 33. Bowie discloses a method for screening ligands for potential pharmaceutical effectiveness and thus does not disclose a formulation including a ligand adapted to target a therapeutic agent. There is no teaching or suggestion in either reference as to why one would add a screening method to the tampon of the Lucas application.

In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

In view of the remarks set forth in this section, Applicants respectfully submit that claim 33 is in condition for allowance and respectfully request favorable consideration and the timely allowance of that claim.

5. Remarks on Paragraph 9 of the Office Action mailed on June 16, 2004: Rejection of Claim 54 as Obvious

In the Office Action mailed June 16, 2004, the Examiner rejects claim 54 as being unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 3,490,454 to Goldfarb et al. ("the Goldfarb patent") in view of U.S. Patent No. 4,726,976 to Karami et al. ("the Karami patent"). Applicants respectfully traverse the rejection.

Again, in order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Piasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Goldfarb patent for modifying its teachings with the teachings of the Karami patent.

Claim 54 is directed to a method of producing an absorbent article configured for partial disposition within the vestibule of a wearer and adapted to deliver a therapeutic agent, the method including treating a portion of a porous nonwoven sheet formed from hydrophobic polymer with a formulation including the therapeutic agent; and forming the absorbent article so as to include absorbent material, such that the absorbent article has an application region for projection within the vestibule, and such that the portion of the porous nonwoven sheet at least partially covers the application region of the absorbent article. Neither of the two cited references (the Goldfarb and Karami patents) disclose the claimed method. The Examiner improperly "picked and chose" the components from the two references using the claimed invention as a template in order to form the rejection.

In the Office Action mailed June 16, 2004, the Examiner states "It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb with a hydrophobic cover layer for the benefits disclosed in Karami." In this Office Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The sole motivation asserted by the Examiner is one of gaining "the benefits disclosed in Karami." It is unclear how reading the "benefits disclosed in Karami" would motivate one to look to another reference. The "benefits disclosed in Karami" purport to be gained by Karami alone. There is also no motivation in the Goldfarb patent to look beyond its four corners to gain any benefits. There is, therefore, no motivation within the patents to apply the teachings of one to the other. The Examiner does not adequately state why one of ordinary skill would read the Goldfarb patent and then look to the Karami patent to convert one method to the another method to arrive at the method of claim 54.

Further, the motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner has pointed to no disclosure within either patent that one of skill in the art would look to for such motivation or teaching. Again, the Examiner has not explained why one would look at method identified in the Goldfarb patent and be motivated to change it by applying the teaching of the Karami patent. The Examiner has failed to identify how the cited reference suggests the desirability of modifying the method of the Goldfarb patent to include components from the Karami

patent. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of claim 54 from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)[2]. For at least these reasons, Applicants assert that a *prima facie* case of obviousness has not been made and that claim 54 is patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that the prior art reference (or references when combined) teach or suggest all the claim limitations. And by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the method of the Goldfarb patent to include components from the Karami patent.

Claim 54 is directed to a method of producing an absorbent article configured for partial disposition within the vestibule of a wearer and adapted to deliver a therapeutic agent, the method including treating a portion of a porous nonwoven sheet formed from hydrophobic polymer with a formulation including the therapeutic agent; and forming the absorbent article so as to include absorbent material, such that the absorbent article has an application region for projection within the vestibule, and such that the portion of the porous nonwoven sheet at least partially covers the application region of the absorbent article. The Goldfarb patent does not teach or suggest all of the claim limitations. First, the Examiner does not assert that the Goldfarb patent discloses every element of claim 54. The Goldfarb patent does not disclose (and the Examiner does not assert that it discloses) an application region for projection within the vestibule, and thus cannot locate a formulation including a therapeutic agent on a porous nonwoven sheet at least partially within that application region. Second, contrary to the Examiner's assertion, the device of the Goldfarb patent is not disclosed as being configured for partial disposition within the vestibule of a wearer. There is no discussion in the Goldfarb patent of a vestibule or any anatomical features (such as labia) associated with a vestibule. The device of the Goldfarb patent has no structure or capability of

[2] "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

being configured for partial disposition within the vestibule, as outlined in the instant application, and the Examiner has not pointed to any disclosure leading to her conclusion. In fact, the Goldfarb patent states that the opposite is the case, that a "particularly preferred type of feminine napkin is of the construction shown in FIGURE 1 which comprises an absorbent portion designated generally as 1 having a shape generally approximating the shape of the exterior surface of the female pubic area to which it is to be applied." (col. 3, lines 18-22; emphasis added). Finally, the stated purpose of the device of the Goldfarb patent is to address menstrual discharge once it is resident in a catamenial product: to obviate odors and to combat bacterial growth within such catamenial product (see col. 1, lines 66-69; col. 2, lines 13-16; col. 2, lines 34-42; col. 5, lines 30-35; among others). There is no substantive disclosure in the Goldfarb patent of treating the user of a catamenial product; consequently, the substances disclosed in the Goldfarb patent are not therapeutic agents. The substances disclosed in the Goldfarb patent are simply chemicals used to deodorize, de-color, or otherwise alter menstrual discharge.

The Karami patent does not correct these deficiencies because it does not teach or suggest a method of producing an absorbent article configured for partial disposition within the vestibule of a wearer and adapted to deliver a therapeutic agent, the method including treating a portion of a porous nonwoven sheet formed from hydrophobic polymer with a formulation including the therapeutic agent; and forming the absorbent article so as to include absorbent material, such that the absorbent article has an application region for projection within the vestibule, and such that the portion of the porous nonwoven sheet at least partially covers the application region of the absorbent article. In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

In view of the remarks set forth in this section, Applicants respectfully submit that claim 54 is in condition for allowance and respectfully request favorable consideration and the timely allowance of that claim.

In conclusion, and in view of the remarks set forth above, Applicants respectfully submit that the application and the claims are in condition for allowance and respectfully request favorable consideration and the timely allowance of claims 1-63. If any additional information is required, the Examiner is invited to contact the undersigned at (920) 721-8863.

The Commissioner is hereby authorized to charge any prosecutorial fees (or credit any overpayment) associated with this communication to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,

DENNIS EVERHART, ET AL.

By: _____

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CERTIFICATE OF FACSIMILE TRANSMISSION

I, Mary L. Roberts, hereby certify that on November 16, 2004 this document is sent by facsimile transmission to the Commissioner for Patents via facsimile number (703) 872-9306.

By: Mary L. Roberts

Mary L. Roberts